Minute Order Form (06/97)

United States District Court, Northern District of Illinois

Name of Assigned Judge or Magistrate Judge	Ronald A. Guzman	Sitting Judge if Other than Assigned Judge	
CASE NUMBER	01 C 1867	DATE	9/27/2004
CASE TITLE	ABBOTT LABORATORIES, et al vs. BAXTER PHARMACEUTICAL PRODUCTS, INC		

[In the following box (a) indicate the party filing the motion, e.g., plaintiff, defendant, 3rd party plaintiff, and (b) state briefly the nature of the motion being presented.]

MOTION:

DOCKET ENTRY:

(1) ☐ Filed motion of [use listing in "Motion" box above.]

(2) ☐ Brief in support of motion due _____.

(3) ☐ Answer brief to motion due_____. Reply to answer brief due_____.

(4) ☐ Ruling/Hearing on _____ set for _____ at _____.

(5) ☐ Status hearing[held/continued to] [set for/re-set for] on _____ set for _____ at _____.

(6) ☐ Pretrial conference[held/continued to] [set for/re-set for] on _____ set for _____ at _____.

(7) ☐ Trial[set for/re-set for] on _____ at _____.

(8) ☐ [Bench/Jury trial] [Hearing] held/continued to _____ at _____.

(9) ☐ This case is dismissed [with/without] prejudice and without costs[by/agreement/pursuant to]
☐ FRCP4(m) ☐ Local Rule 41.1 ☐ FRCP41(a)(1) ☐ FRCP41(a)(2).

(10) ■ [Other docket entry] ENTER MEMORANDUM OPINION AND ORDER: The Court grants Abbott's motion in limine to bar the introduction by Baxter of any evidence of its alleged ability or inability to produce a generic sevoflurane with a water level of not more than 130 ppm [doc. no. 161].

(11) ■ [For further detail see order attached to the original minute order.]

	No notices required, advised in open court.		number of notices
	No notices required.		
	Notices mailed by judge's staff.		SEP 2 8 2004 date docketed
	Notified counsel by telephone.		
✓	Docketing to mail notices.		JXM docketing deputy initials
	Mail AO 450 form.		
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Document Number

200

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ABBOTT LABORATORIES, an Illinois Corporation, and CENTRAL GLASS COMPANY LTD., a Japanese Corporation,	)	
Plaintiffs,	)	
v.	)	**Judge Ronald A. Guzmán**
BAXTER PHARMACEUTICAL PRODUCTS, INC., a Delaware Corporation, and BAXTER HEALTHCARE CORP., a Delaware Corporation,	)	**01 C 1867**
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Plaintiffs Abbott Laboratories and Central Glass Company Ltd. have moved in limine to bar the introduction by Defendants Baxter Pharmaceutical Products, Inc. and Baxter Healthcare Corp. of any evidence of defendants' alleged ability or inability to produce a product with a water level not more than 130 parts per million ("ppm") because of commercial impracticability. For the reasons provided in this Memorandum Opinion and Order, the Court grants Plaintiffs' motion in limine to bar any evidence of defendants' ability or inability to manufacture generic sevoflurane with a water content of not more than 130 ppm.

FACTS

Sevoflurane is a fluorine-based inhalation anesthetic first developed by Baxter in the mid-1960's. It is used as a general anesthesia for patients undergoing surgery. The

original patent on sevoflurane has long since expired, and due to a complicated licensing agreement, Abbott Laboratories is the sole seller of sevoflurane in the United States until December 2005. Abbott has several patents for inhibiting degradation of liquid sevoflurane by Lewis acids, which can result in harmful by-products. In order to prevent degradation, Abbott determined that a Lewis acid inhibitor (one of which is water) could be added to the sevoflurane. Abbott's U.S. Patent No. 5,990, 176 ("the '176 patent") teaches that to stop degradation, an effective stabilizing amount of Lewis acid inhibitor must be added to the sevoflurane.

This complaint arises out of an Abbreviated New Drug Application ("ANDA") filed by Baxter in June 2000 seeking approval to sell generic sevoflurane with a water level of not more than 130 ppm in aluminum containers lined with an epoxyphenolic liner. In its ANDA, Baxter made a paragraph IV certification that its generic sevoflurane does not infringe the '176 patent. Abbott filed suit alleging infringement of the '176 patent under the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2). The Court granted Baxter's motion for summary judgment, limiting the meaning of "effective amount" to amounts greater than 130 ppm due to a disclosure made by Abbott during patent prosecution that sevoflurane was sold at a level of 131 ppm more than one year prior to filing it patent application. *Abbott Labs. v. Baxter Pharm. Prods.*, No. 01 C 1867, 2002 WL 449007 at *6 (N.D. Ill. Mar. 22, 2002), *vacated and remanded by Abbott Labs. v. Baxter Pharm. Prods., Inc.*, 334 F.3d 1274 (Fed. Cir. 2003). The Federal Circuit vacated and remanded the case, disagreeing with the Court's decision restricting effective amounts to those above 130 ppm and interpreting the scope of claims 1 and 6 of the '176 patent "to a single Lewis acid inhibitor selected from the recited Markush group, and present in an amount

effective to prevent degradation of sevoflurane by Lewis acids." *Abbott Labs.*, 334 F.3d at 1281.

DISCUSSION

Baxter's ANDA submission and paragraph IV certification that its proposed generic sevoflurane product does not infringe the '176 patent creates an artificial act of infringement under 35 U.S.C. § 271(e)(2). *See Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990) (noting that submission of an ANDA creates a "highly artificial act of infringement"); 35 U.S.C. § 271(e)(2)(A) ("It shall be an act of infringement to submit . . . an [abbreviated new drug] application under [21 U.S.C. § 355(j)] . . . for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.")

Plaintiffs and defendants agree that infringement in this case is based upon the limitation supplied in defendants' ANDA that sevoflurane will have a water content of 130 ppm or less. (*See* Pls.' Reply Baxter's Resp. Mot. Limine (I) at 2 ("The determination of literal infringement rests on whether Baxter's amended ANDA with 130 ppm water level infringes the '176 patent."); Baxter's Sur-Reply Mem. Opp'n Pls.' Mot. Limine (I) at 1 ("Because this is a Hatch-Waxman Case, infringement is judged based on the description of Baxter's proposed sevoflurane product in Baxter's ANDA.").) The issue raised in the instant motion in limine and memorandum in support is whether Baxter may provide evidence of an ability or inability to produce a product with a water

level not more than the 130 ppm limitation imposed by their ANDA. Baxter responds that no evidence will be submitted on an inability to produce a product with a water level of not more than 130 ppm, but that defendants will introduce evidence that they do in fact have the *ability* to produce generic sevoflurane at levels below 130 ppm. Baxter has misconstrued Abbott's motion in limine in which Abbott requests that the Court bar Baxter from introducing any evidence of an inability *or ability* to produce generic sevoflurane with a water level of not more than 130 ppm. (*See* Pls.' Mot. Limine (1) at n.1 (arguing that "[a] water level below 130 ppm has no bearing on [infringement]" and quoting Baxter's Proposed Finding of Fact 2 on non-infringement which states that "sevoflurane can be made with little or no water and still meet the specification set forth in Baxter's ANDA").) This motion turns on whether Baxter's ability or inability to produce generic sevoflurane at a water content of less than 130 ppm is relevant to the issue of infringement.

Federal Rule of Evidence 401 defines relevant evidence as "evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Fed. R. Evid. 401. Baxter's ability or inability to manufacture generic sevoflurane with a water content of not more than 130 ppm is not relevant in this case. Baxter contends that it will not even offer any such evidence on its inability. (Baxter's Resp. Pls.' Mot. Limine (I) at 1.) Whether Baxter has the ability to produce generic sevoflurane with a water level of not more than 130 ppm is also not relevant in this case. As noted above, an action brought under § 271(e) constitutes an artificial act of infringement. In this case, infringement will be determined at the 130 ppm limitation noted in Baxter's ANDA.

Baxter argues that their ANDA specifies sevoflurane having not more than 130 ppm of water and that infringement then involves sevoflurane with 130 ppm of water *or less*. Baxer's reasoning is misguided. Patent infringement in such a scenario is defined by the specification in the ANDA itself. *See Abbott Labs. v. TorPharm, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002) (noting that "an ANDA specification defining a proposed generic drug in a manner that directly addresses the issue of infringement will control the infringement inquiry.") The ANDA specification in this case defines Baxter's sevoflurane product with a water content of not more than 130 ppm, which directly addresses the issue of infringement, as the '176 patent teaches the use of water as a Lewis acid inhibitor. The product that Baxter actually manufactures is not an issue in this case. The act of infringement is defined by the ANDA itself, and if a 130 ppm water content is effective as a Lewis acid inhibitor, it is irrelevant whether Baxter could produce sevoflurane with a water content of 100 ppm, 65 ppm, or even 0 ppm.

Under literal infringement or under the doctrine of equivalents, the ultimate issue must be addressed with regard to a 130 ppm water content. As noted by the Federal Circuit, to prove infringement "Abbott must show a species selected from the members of the recited Markush group [*i.e.*, water] is present in Baxter's sevoflurane composition in an amount *effective* to function as a Lewis acid inhibitor." *Abbott Labs.*, 334 F.3d at 1283 (emphasis added). Literal infringement then turns on whether a water content of 130 ppm, as specified in its ANDA, is effective as a Lewis acid inhibitor. Baxter's theories of non-infringement do not alter this viewpoint. First, Baxter contends that a person of ordinary skill in the art would not be able to determine this "effective" amount beforehand because effectiveness is dependent on the "particular circumstances" of the

sevoflurane at issue. Next, Baxter contends that its proposed sevoflurane product does in fact degrade when it is exposed to Lewis acids, and that the water content must therefore not be effective. Finally, Baxter argues that Abbott made statements to the FDA indicating that a water content of 130 ppm is not effective to prevent degradation. None of these theories of literal infringement require any evidence that Baxter could produce generic sevoflurane with a water content below 130 ppm. Under the doctrine of equivalents the same holds true, and the 130 ppm specification from Baxter's ANDA will be the water content that is considered by the Court.

Baxter also mistook Abbott's request to bar evidence of Baxter's ability or inability to produce generic sevoflurane with a water level of not more than 130 ppm with a request to bar *any* evidence of a water level below 130 ppm. Indeed, *some* evidence regarding a water level below the 130 ppm limitation outlined in Baxter's ANDA may be relevant. For example, evidence of water content that falls below the ANDA limitation of 130 ppm may establish effective lower limits of water required to inhibit Lewis acids in Baxter's proposed lined container. Abbott's own expert reported testing results on a sample of Baxter's sevoflurane having a water content of 60 ppm. (Baxter's Sur-Reply Mem. Opp'n Pls.' Mot. Limine (I) at 2.) Ultimately, of course, infringement will be determined at a water level of 130 ppm, per Baxter's ANDA, but barring *any* evidence of a lower water concentration is not warranted in this case.

This Court grants Plaintiffs' Motion in Limine (I). Baxter is barred from introducing any testimony on its ability or inability to produce a product with a water level of not more than 130 ppm, per its ANDA.

CONCLUSION

For the foregoing reasons, the Court grants Abbott's motion in limine to bar the introduction by Baxter of any evidence of its alleged ability or inability to produce a generic sevoflurane with a water level of not more than 130 ppm [doc. no. 161].

SO ORDERED **ENTERED:** 9/27/04

HON. RONALD A. GUZMAN
United States Judge